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| 10/622,207  | 07/18/2003  | Edwin J. Hlavka      | MICO-06C            | 4023             |
| 26875 7590 05/12/2009<br>WOOD, HERRON & EVANS, LLP<br>2700 CAREW TOWER<br>441 VINE STREET<br>CINCINNATI, OH 45202 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| MATTHEWS, WILLIAM H   |             |                      |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/622,207  
Filing Date: July 18, 2003  
Appellant(s): HLAVKA ET AL.

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David Dorton  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 12-9-09 appealing from the Office action mailed 9-2-08.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 60-67 and 69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification and drawings fail to support three or more fasteners **coupled with** a tensioning element (claim 60, line 8).

Claims 60-67 and 69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As the specification fail to disclose fasteners coupled to the tension element, the specification fails to enable one of ordinary skill in the art to make or use the invention as claimed.

#### **(10) Response to Argument**

Appellant contends that support for *a tensioning element coupled with fasteners* is disclosed in the originally filed disclosure at page 15, line 23 through page 16, line 4. This portion of the specification describes three elements pertinent to the issue under appeal: a tensioning element 1140 (e.g. a string), fasteners 1012 (T-bar anchors), and a tubular implant 1124. The fasteners 1012 attach, or couple, the implant 1124 to tissue and then a tensioning element 1140 is passed through the lumen of tubular implant 1124 as shown in Figure 11B below.

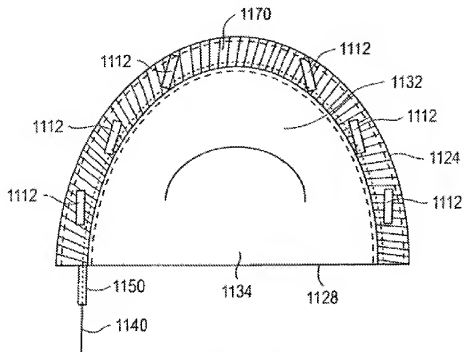
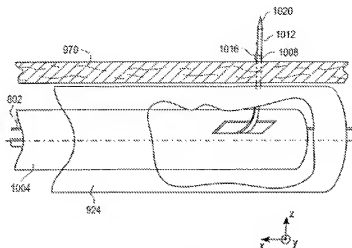


FIG. 11b

However, the specification only provides the term "coupled" to describe an attachment of parts wherein intimate contact occurs, and such terminology is not used to describe the arrangement between the tensioning element and fasteners. For example, the Specification at page 15 lines 1-2 describes a coupled arrangement of the fasteners 1012 with extension 1016 as shown in Figure 10 (note extension 1016 is a portion of the delivery mechanism unrelated to the claimed tensioning element 1140):

bar 1012. T-bar 1012 is coupled to an extension 1016 which may be used to effectively tie off T-bar 1012 such that T-bar 1012 holds implant 924 against fibrous tissue 970 around the mitral valve. Typically, a pointed or sharpened end 1020 of



Continuing, Appellant describe in the Specification at page 15 lines 23-28 the relationship between the fasteners 1012 and the heart valve tissue as being coupled and that such devices are termed coupling devices:

described in accordance with an embodiment of the present invention. An implant 1124 is positioned under a mitral valve 1128, *i.e.*, in a left ventricle of a heart, and is held against mitral valve 1128 using coupling devices 1112 that effectively attach implant 1124 to fibrous tissue 1170. In the described embodiment, coupling devices 1112 are T-bars, although it should be understood that other coupling devices, *e.g.*, staples or barbs, may be used in lieu of T-bars.

Thus it is apparent from Appellant's specification that the term ***coupled*** should be interpreted as including intimate contact and attachment. The tensioning element of Appellant's invention is not disclosed to be in intimate contact with or attachment to the tubular implant 1124, rather it merely passes through. Furthermore, there is no suggestion or disclosure to connect, contact, or couple the tensioning element to the fasteners.

Examiner maintains that the term "coupled" is inappropriate for the relationship between the tensioning element and fasteners. At best, the disclosure would support an indirect coupling by way of the implant, which is suggested in the Brief at page 7, second paragraph:

The Application at page 15, line 23, through page 16, line 4, describes how fasteners (e.g., T-Bars 1112) are coupled with the tensioning element 1140 by way of the implant 1124. Specifically, the T-Bars 1112 secure the implant 1124 to the tissue, and the tensioning element 1140 is inserted within the implant 1124. The implant may

However, "an indirect coupling" remains questionable as such an interpretation would be analogous to describing gumballs in a gumball dispenser having a knob as having gumballs indirectly coupled to a knob by way of the dispenser. Examiner asserts that the reasonable definition of coupling, as supported by Appellant's own specification, requires more than mere positioning of an element with respect to another, such as intimate contact and attachment.



**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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/Thomas C. Barrett/  
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